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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 07/838,675 | 02/21/92 | FALK | R PT-1039 |

| EXAMINER | |
|---|---|
| FONDA, K | |
| **ART UNIT** | **PAPER NUMBER** |
| 1211 | 28 |

12M2/0416

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**DATE MAILED:** 04/16/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11-16-95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), ——— days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☒ Status inquiry rec'd 2-15-96.

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-17 and 21-25 are pending in the application.
   Of the above, claims 1-5 and 21-25 are withdrawn from consideration.
2. ☒ Claims 18-20 and 26 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 6-17 are rejected.
5. ☒ Claims 13 is ~~are~~ objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

The Group Art Unit assignment of this application has changed. To aid in association of papers with the file, it is requested that any future communications from Applicant reference Art Unit 1211.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The objection to the Abstract is withdrawn.

The oath or declaration is still held to be defective, for the reasons set forth in item 17 of the Office action mailed 05-17-95. Applicant's statement that a new oath or declaration is being prepared is noted.

Applicant's statement regarding the incomplete literature citations in the specification is noted. The requested to complete the citations is maintained.

Claim 13 is objected to because in line 10, "comrising" should be --comprising--.

The specification is objected to under 35 U.S.C. § 112, first paragraph, because the specification, as originally filed,

does not provide support for the invention as is now claimed. Specifically, no support is seen for the recitation in claim 6 that the effective dosage amount for treatment of basal cell carcinoma comprise "at least 30-60 mg of a form of hyaluronic acid". Applicant attempts to justify recitation of this dosage amount in the first and second full paragraphs on page 16 of the response of 11-16-95. Applicant states, in essence, that because 2 grams of the composition were administered according to page 50, line 7, of the specification, and because the percentage range of hyaluronic acid in the composition is 1.5% to 3%, the amount of hyaluronic acid administered for treatment of basal cell carcinoma must be 30-60 mg. While Applicant's calculation is numerically correct, this conclusion is erroneous because the specification does not teach that 2 grams is the amount of composition to be applied for treatment of basal cell carcinoma. The 2 gram amount referred to on page 50 was used in a test to determine blood levels of diclofenac in **healthy test subjects** after topical administration of a formulation of diclofenac and hyaluronic acid; see page 40, line 25 to page 50, line 9. This clearly does not constitute a teaching of an amount suitable for treatment of any disorder. In the second full paragraph on page 17 of the reply of 11-16-95, Applicant states that persons skilled in the art "would use the exemplary amounts provided in the specification". The Examiner continues to maintain, as set

forth in the previous Office action, that no exemplification or teaching of amounts for treatment of basal cell carcinoma have been provided.

Claims 6-12 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the preceding paragraph. This is a new matter rejection.

The objection to the specification and rejection of claims 6-17, under 35 U.S.C. § 112, first paragraph, is maintained for the reasons set forth in sections 23B and 23C of the Office action mailed 05-17-95. The objection and rejection for the reasons set forth in section 23A is withdrawn.

Applicant's arguments filed 11-16-95 have been fully considered but they are not deemed to be persuasive with regard to the rejection as set forth in items 23B and 23C.

Applicant is directed to the above comments with regard to the lack of an enabling teaching of how much of the formulation of the instant invention to use for treatment of basal cell carcinoma; these comments are also relevant to the instant rejection.

Applicant argues at the top of page 18 of the response filed 11-16-95 that the blood level tests indicate that "amounts from the formulation" would be effective. This is not convincing for at least two reasons. The first is, as set forth above, that

there is no clear teaching of what these "amounts" should be for treatment of basal cell carcinoma. The second is that both Applicant's specification and Applicant's remarks urge that the compositions of the instant invention are locally acting, not systemically dispersed through the bloodstream, and eventually cleared through the lymphatic system; see, for example, the paragraph bridging pages 23-24. It should be noted that the point of the blood level tests was to demonstrate that compositions of the instant invention **did not** transport NSAIDs into the bloodstream to as great an extent as other topical formulations. Thus it is not seen that these results would indicate anything at all concerning treatment of basal cell carcinoma to the skilled worker in the art.

Applicant refers to a number of additional patents or published patent applications which, according to Applicant, indicate that one skilled in the art could use the invention for treatment of basal cell carcinoma. These documents are accorded little weight because they are not in declaration form. With regard to any such declarations which may later be submitted, Applicant is reminded that what must be established is that the invention as claimed was enabled as of Applicant's U.S. filing date.

Claims 6-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The claims are newly rejected because the two independent claims (6 and 13) have been amended to include the phrases "a number of times daily" and "over a prolonged period of time". The Examiner notes that literal support is provided in the specification for these phrases. However, because the phrases have no particular art-recognized meaning, and because the specification does not define them, the metes and bounds of the claims cannot be determined.

Claim 13 is further newly rejected because the phrase "including any scar tissue" at lines 13-14 is unclear as to whether it is intended as an exclusive description of the claimed subject matter. The claim is therefore considered to be indefinite.

Claims 8 and 12 are again considered to be vague and indefinite as to the method by which the molecular weight is determined, as set forth in item 25B of the previous Office action. Applicant's arguments filed 11-16-95 have been fully considered but they are not deemed to be persuasive with regard to this rejection. Applicant, apparently having misunderstood the rejection, states that no experimentation is required to

determine the molecular weight because the information could be provided by the manufacturer. It should be noted that the issue of this rejection is one of definiteness of claim language, and not enablement. That a manufacturer may know the molecular weight of its product is not relevant. What is required is that Applicant clearly indicate, in a manner supported by the specification as originally filed, what is intended by the recitation of "molecular weight". Those of skill in the art recognize that there are a number of methods for determining and reporting molecular weights of polymers, such as number-average molecular weight and weight-average molecular weight, and that these methods give different values. The metes and bounds of the claims are unclear unless there is some indication of how the molecular weight of the hyaluronic acid of the claims is determined.

Claim 6 is again considered to be vague and indefinite with regard to whether or not the remaining parenthetical expressions are intended as claim limitations.

The Examiner agrees that the drug names used in the pending claims are generic, and not trademarks or trade names. To avoid implying otherwise, Applicant is requested to amend the claims to refer to these drugs using all lower case letters.

All grounds of rejection under 35 U.S.C. § 112, second paragraph, made on page 9 of the Office action of 05-17-95 and not reiterated in the instant Office action are withdrawn.

The rejections under 35 U.S.C. § 103 are withdrawn because the DELLA VALLE and SCHULTZ references relied on do not teach or suggest a method of treating basal cell carcinoma which consists essentially of topical administration of hyaluronic acid and a prostaglandin-inhibiting drug. It is not considered relevant that the prior art may not have recognized the inherent properties of hyaluronic acid as a transport agent.

Claims 6-17 are again provisionally rejected under the judicially created doctrine of obviousness-type double patenting as set forth in item 31 of the Office action of 05-17-95. Applicant has not addressed these provisional rejections. The Examiner acknowledges Applicant's statement that the rejections will be addressed at a later time.

The Examiner acknowledges Applicant's statement in response to the requirement in item 35 that the commonly assigned cases have always been commonly held.

No claim is allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers relating to this application may be submitted to Group 1200 by facsimile transmission. The number of the fax machine for official papers in Group 1200 is (703) 308-4556. The cover sheet of any document submitted by facsimile transmission should be clearly marked as either an official or an informal communication.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached from Monday through Thursday, as well as on alternate Fridays, between 7:30 a.m. and 5:00 p.m. If the Examiner cannot be reached, questions may be addressed to

Supervisory Patent Examiner John Kight, at (703) 308-0204. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1200 receptionist whose telephone number is (703) 308-1235.

KKF
Kathleen Kahler Fonda, Ph.D.

Gary L. Kunz

GARY L. KUNZ
PRIMARY EXAMINER
GROUP ~~1800~~ 1200